TILLOTSON HEALTHCARE CORPORATION

A Trusted Name in Healthcare Products

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January 21, 2000

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Re: Docket No. 99N-4487: Medical Devices; Draft Guidance for Conducting Stability Testing to Support an Expiration Date Labeling Claim for Medical Gloves; Availability

Dear Madam or Sir:

These comments are submitted by Tillotson Healthcare Corporation (THC) in response to the Food and Drug Administration's (FDA) draft guidance on expiration dating of medical gloves. See 64 Fed. Reg. 41,709 (July 30, 1999). THC is a New Hampshire-based Corporation and a manufacturer of medical gloves.

I. THC does not oppose expiration date labeling of medical gloves, but believes there is an inadequate scientific basis to support FDA's two year expiration date period for Medical Gloves.

The FDA's draft guidance would not allow a provisional shelf-life labeling claim to exceed a period of 2 years if it is established based on

99D-4487 C1

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accelerated aging test data. THC does not believe that a two year period for accelerated aging claims is long enough for a typical glove product out in the market. In THC's view, consideration should be given to a 3 year provisional expiration date base on accelerated heat-aging data.

II. THC believes that FDA should support current accelerated aging protocols based on the Arrhenius model for determining expiration dating of medical gloves.

In THC's view, FDA and glove manufacturers should support the development of an official ASTM standard for accelerated aging of medical gloves for expiration dating. Until such a test method is established, manufacturers should be allowed to use available accelerated heat-aging Q10=2 Arrhenius protocols for the prediction of gloves shelf-life.

III. THC believes that FDA should define ambient temperature as it applies to accelerated aging protocols based on the Arrhenius model for determining expiration dating of medical gloves.

The FDA's draft guidance does not define ambient temperature as it is applied to shelf-life analysis. THC requests that FDA define ambient temperature with a range that would accommodate the diverse climate of South East Asia and the USA. THC's view is that a range of ambient temperature between 20 C to 35 C would be practical.

IV. In establishing the time of gathering gloves for expiration date testing, the FDA proposes that all gloves be tested within 96 hours of manufacture. THC urges the FDA to allow product to be tested in the US after shipment from a factory in the Far East.

The FDA's draft guidance defines the date of manufacture to be the date the product was initially packaged. This means that time zero baseline tests must be completed within 96 hours. THC's view is that it will be very difficult for USA manufacturers' to perform shelf life studies on their gloves that are made in Malaysia since it takes several weeks for product to arrive on USA shores. Further, the FDA is proposing that the real time aging conditions begin with the conditions the product is exposed to during transportation and continue with the conditions they will

be exposed to during warehouse storage. For manufacturers that perform testing in the US after product has been subjected to real life conditions of shipment, real time studies should be allowed to start at this point and not be required to additionally simulate the theoretical transportation conditions. THC believes that to require so would be impractical for product shipped from South East Asia to USA shores. This impose an excessive burden for USA manufacturers to shelf-life test gloves in the USA.

V. The FDA proposes that gloves be tested for real-time shelf-life aging every 6 months. THC suggests that the FDA to allow product to be tested every 12 months after manufacture.

The FDA's draft guidance proposes that the manufacturer test their gloves for real-time shelf-life aging every 6 months. THC does not believe that their is an adequate scientific basis for shelf-life testing gloves every 6 months. THC encourages the FDA to adopt a more practical testing schedule of every 12 months. In addition, when physical properties such as tensile strength at break are tested, it is typical to take 3 dumbbells from each glove sample and determine the median value. It is unreasonable for the FDA to ask for justification if more than one

specimen is taken from each glove. THC supports the testing of more than one glove specimen, but does not support any restriction on the number of test dumbbells per glove. The FDA's draft guidance proposes that the manufacturer test their gloves at a documented temperature. THC believes that the temperature for testing the physical properties of gloves should be ambient in the range of 20 C to 35 C.

VI. The FDA proposes that sterile glove packaging be tested for package integrity and the ability to maintain sterility to determine shelf-life. In THC's view, sterility testing is the main issue, and if the sterility of the package is maintained then package integrity testing is not necessary.

THC supports sterility testing of sterile glove packages for the determination of shelf-life and an expiration date. But it is unnecessary for the FDA to propose that sterile glove packaging be tested for package integrity as well. In THC's view, sterility testing is the main issue, and if the sterility of the package is maintained then a package integrity or seal strength test is not necessary.

THC appreciates the opportunity to provide comments on the FDA's proposed draft guidance on glove expiration dating. Should there be any questions on the our comments, please feel free to contact us.

Respectfully submitted,

F.W. Perrella, Ph.D.
Vice President of R & D
Tillotson Healthcare Corporation

SPH43

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